

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA  
MIAMI DIVISION

UNITED STATES OF AMERICA  
ex rel.

VEN-A-CARE OF THE FLORIDA  
KEYS, INC., a Florida corporation, by  
and through its principal officers and  
directors, ZACHARY T. BENTLEY and  
T. MARK JONES,

Plaintiff,

v.

ABBOTT LABORATORIES, INC. and  
HOSPIRA, INC.,

Defendants.

Case No.: 06-CV-21303-ASG

Hon. Alan S. Gold

**DEFENDANT ABBOTT LABORATORIES INC.'S FIRST SET OF REQUESTS  
FOR PRODUCTION OF DOCUMENTS AND TANGIBLE  
THINGS TO PLAINTIFF UNITED STATES OF AMERICA**

Defendant Abbott Laboratories, Inc. ("Abbott"), pursuant to Rule 34 of the Federal Rules of Civil Procedure, requests that Plaintiff the United States of America produce the documents requested herein by making them available for inspection and copying at the offices of Jones Day, 51 Louisiana Ave., NW, Washington, DC 20001, or at such other place and in such manner as may be mutually agreed upon between counsel for the parties, within thirty (30) days from the date of service of these Requests.

**DEFINITIONS**

1. "Abbott" means Abbott Laboratories, Inc. and Abbott Laboratories and any of their past or present officials, officers, representatives, agents, assigns, attorneys, employees, divisions, departments, agencies, affiliates, subsidiaries, and all other persons or entities acting or purporting to act on their behalf or under their control.

## **DOCUMENTS REQUESTED**

### **Category 1: General**

1. All Documents mentioned in or referred to in preparing Your response to any set of interrogatories or requests for admission served by Abbott in this case.

2. For the period January 1, 1980 to the end of the Relevant Claim Period, Documents, such as current or historical organizational charts, sufficient to identify all individuals involved in establishing the methodologies, policies, and procedures used in determining payment of drugs under Medicare Part B.

3. For the period January 1, 1980 to the end of the Relevant Claim Period, Documents, such as current or historical organizational charts, sufficient to identify all individuals involved in establishing the methodologies, policies, and procedures used in determining payment of drugs under Medicaid.

4. For the period January 1, 1980 to the end of the Relevant Claim Period, Documents, such as current or historical organizational charts, sufficient to identify all individuals involved in establishing the price at which the U.S. Government (*e.g.*, VA, Department of Defense) purchased drugs directly or indirectly from Manufacturers, distributors, or wholesalers.

5. For the period January 1, 1980 to the end of the Relevant Claim Period, Documents, such as current or historical organizational charts, sufficient to identify all individuals involved in establishing the price at which state governments purchased drugs directly or indirectly from Manufacturers, distributors, or wholesalers.

### **Category 2: Claims Data and Processing**

6. For each Medicare and Medicaid transaction during the Relevant Claim Period relating to the Subject Drugs and Equivalent Drugs, complete claims data with related field definitions, data dictionaries, source tables, relationship tables, and business rules for all populations for which damages are being alleged. This data is requested in electronic form used by SQL Server, Microsoft Access, Microsoft Excel, or a delimited file that can be readily uploaded into one of those programs. The complete claims data requested includes all fields, other than individual patient identifiers, contained on the Provider's claim submission and all additional fields added to process the claim, including:

- (a) *Identifier*: claim number, sequence number representing each line item of the claim, and other identifying information;
- (b) *Claim Type*: physician supplier, outpatient hospital, physician crossover, etc.;

- (c) *Transaction Type*: all available transaction type information, such as correction, cancellation, etc., identifiers, and source transaction information (e.g., if one claim corrects another claim, information about which claim is being corrected);
- (d) *Status*: all status information, including the payment code indicating whether the claim has been accepted, processed, and/or paid and the type of program the claim will be processed under (e.g., Medicaid, Managed Care, etc.);
- (e) *Dates*: all available dates, including the date service was provided, the date the claim was received, and the date the claim was paid;
- (f) *Basis of payment*: coding within the claim payment transaction which identifies the reference point from which the claim payment amount is determined (e.g., AWP, usual & customary);
- (g) *Provider*: all information for all relevant Providers, including Provider type (e.g., hospital, retail pharmacy, etc.), number, name, address, contact information, and area/field of practice (where relevant);
- (h) *Product*: all product information, including:
  - (i) HCPCS code where applicable;
  - (ii) NDC whenever available, including where available for non-pharmacy claims (e.g., from memo field, supplemental provider submissions and/or HCPCS code translations). Provide all 11 digits (do not drop leading or trailing 0's) and ideally in three separate fields – labeler (first five digits), product (next four digits) and package size (final two digits);
  - (iii) Name;
  - (iv) Type (e.g., single source, multi-source);
  - (v) Therapeutic class; and
  - (vi) Related items like diagnosis codes, place of service, and type of service (where relevant).
- (i) *Units*: all units information with decimals in the correct position, including submitted units, allowed units, and unit of measure (e.g., capsule vs. bottle, milliliter, etc.);
- (j) *Other Data for Payment*: any other data used to determine the amount of the payment not listed above (e.g., channel of procurement, etc.);

- (k) *Payments*: all fields related to billed amounts, payment limit amounts, allowed amount, and actual amounts paid along with the bases for the payment, all with decimals in the correct position, including:
  - (i) Drug cost (basis of payment might include EAC, FUL, MAC, Billed Amount, Charges, Cost, AWP, WAC, etc.);
  - (ii) Dispensing fee;
  - (iii) Service administration fee (*e.g.*, provider service fees);
  - (iv) Any other payment amount (*e.g.*, inventory management fee/profit factor, delivery fee, generic incentive fee, etc.); and
  - (v) Any amounts used to reduce amount paid (*e.g.*, payments received from other payors and the number, name, and other information associated with such payors).
- (l) *Comments*: all other memo or free-form fields (*e.g.*, Item 19 of the HCFA-1500).

7. For each year and for each time within each year that a calculation was made, all Documents concerning how each Medicare Carrier calculated the median AWP or, when applicable, the "lowest branded AWP" for the Subject Drugs. *See* 42 C.F.R. 405.517(c).

8. For each year and for each time within each year that a calculation was made, all Documents concerning how each Medicare Carrier and Medicaid Intermediary determined payment amounts for the Subject Drugs and the Equivalent Drugs.

9. For each Medicare and Medicaid claim You allege to have been inflated and for which You are seeking damages or statutory penalties, all Documents concerning how You determined the Provider's actual acquisition cost and/or the amount by which the claim was inflated.

10. All drug fee schedules concerning the Subject Drugs and the Equivalent Drugs, including all updates, revisions, or corrections.

11. To the extent not requested above, all Documents that reflect the losses, damages, or alleged overpayments made by the U.S. Government as a result of Abbott's alleged conduct.

12. From January 1, 1965 to the end of the Relevant Claim Period, all Documents relating to any Communications between the U.S. Government and Medicare Carriers, State Medicaid Programs, Medicaid Intermediaries, NAMFCU, MFCUs, the National Association of State Medicaid Directors, or the National Governors Association concerning the methodologies, policies, and procedures to be used in determining payment for drugs under Medicare Part B or

Medicaid, including but not limited to Medicare Part B Newsletters, Program Memoranda, National Coverage Decisions, Local Medical Review Policies, Bulletins, meetings, seminars, circulars, governmental reports, or any transmission of data.

13. All State Medicaid Program plans, under 42 U.S.C. § 1396(a), and other documents concerning how Medicaid Intermediaries or State Medicaid Programs calculated or determined payment amounts for the Subject Drugs or the Equivalent Drugs, including all policy and procedure manuals, proposals, drafts, and working papers.

14. To the extent not requested above, all Documents concerning the methodologies, policies, and procedures to be used in determining payment for drugs under Medicare Part B or Medicaid. Such documents should include the source (e.g., Red Book, Blue Book, Medispan) of AWP, WAC, or other figure if reimbursement was based on such figures.

15. All Documents concerning how State Medicaid Programs paid 340B Providers for supplying or administering drugs to Medicaid beneficiaries.

16. For each quarter during the Relevant Claim Period, Documents sufficient to identify the Federal Medical Assistance Percentage ("FMAP") applicable to each State Medicaid Program.

17. For each quarter during the Relevant Claim Period, Documents sufficient to show how Medicare Carriers or Medicaid Intermediaries calculated any FUL applicable for the Subject Drugs or the Equivalent Drugs.

18. From January 1, 1965 to the end of the Relevant Claim Period, all Documents concerning any audit, report, study, analysis, or survey (whether completed or not) concerning the differences in the amounts that Medicare Carriers or Medicaid Intermediaries paid for the Subject Drugs or Equivalent Drugs under Medicare Part B or Medicaid, including but not limited to all Documents concerning differences in how Medicare Carriers or Medicaid Intermediaries calculated the median AWP or "lowest branded AWP." See 42 C.F.R. 405.517(c).

**Category 3: Government Drug Payment Analyses and Contracts**

19. From January 1, 1965 to the end of the Relevant Claim Period, all Communications involving any Person working for or on behalf of the U.S. Government, any state government or State Medicaid Program, MedPac, NAMFCU or any MFCU, any Provider, any Publisher, or any Manufacturer concerning (i) the methodologies, policies, and procedures to be used in determining payment for drugs under Medicare Part B or Medicaid, (ii) drug pricing, or (iii) the acquisition costs of Providers for drugs.

20. From January 1, 1965 to the end of the Relevant Claim Period, all Documents relating to any report, memorandum, audit, study, analysis, or survey (whether completed or not) concerning (i) the methodologies, policies, and procedures to be used in determining